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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

EPDS, JANET L

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 06/26/2003

141

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/823,119

Applicant(s)

KAPLOW ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, 3, and 26-28, drawn to an isolated nucleic acid encoding NFIF-14b, classified in class 536, subclass 23.1.
  - II. Claims 2, 4, and 30-32, drawn to an isolated nucleic acid encoding NFIF-7a, classified in class 536, subclass 23.1.
  - III. Claims 5, and 25 drawn to an isolated and purified NFIF-14b polypeptide, classified in class 530, subclass 350.
  - IV. Claims 6, and 29 drawn to an isolated and purified NFIF-7a polypeptide, classified in class 530, subclass 350.
  - V. Claims 7-9, and 12, drawn to a method of increasing expression of NF $\kappa$ B in a patient comprising introducing an expression vector encoding NFIF-14b polypeptide, classified in class 435, subclass 375.
  - VI. Claims 7, 10-11, and 13, drawn to a method of increasing expression of NF $\kappa$ B in a patient comprising introducing an expression vector encoding NFIF-7a polypeptide, classified in class 435, subclass 375.
  - VII. Claims 14 and 16 drawn to a composition for lowering the expression of NFIF in a patient comprising an antisense or ribozyme, classified in class 536, subclass 24.5.

- VIII. Claim 15 drawn to a composition for lowering the activity of an NFIF polypeptide in a patient comprising a neutralizing antibody that binds to an NFIF polypeptide, classified in class 530, subclass 387.1.
- IX. Claims 17, 19, 21, and 23 drawn to a method for evaluating whether a test compound is effective in inhibiting the activity of NFIF-14b, classified in class 435, subclass 6.
- X. Claims 18, 20, 22, and 24, drawn to a method for evaluating whether a test compound is effective in inhibiting the activity of NFIF-7a, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-II and V-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid molecules of inventions I-II can be used in a materially different process than in the methods of inventions V-VI (respectively). For example, the nucleic acid molecules of inventions I-II can be used in a method for producing an NFIF polypeptide.

3. Inventions III-IV, VIII and Inventions IX -X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the polypeptides of inventions III-IV can be used in a materially different method than in the methods of inventions IX-X. For example, the polypeptides can be used for the manufacture of a medicament intended for the treatment and/or prevention of an NF- $\kappa$ B-regulated inflammatory response. The composition comprising a neutralizing antibody of invention VIII can be used in a method materially different from the methods of inventions IX-X, for example this composition can be used for detecting the presence of an NFIF polypeptide in a sample.

4. Inventions I-IV, and VII-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, inventions I-IV, and VII-VIII are drawn to chemically and structurally distinct biological molecules, possessing distinct functions and modes of activity. Invention I is drawn to a nucleic acid having a nucleotide structure according to SEQ ID NO: 1, invention III is drawn to the NFIF-14b polypeptide encoded by this nucleotide sequence. Invention II is drawn to a nucleic acid sequence having a nucleotide structure according to SEQ ID NO: 2, invention IV is drawn to the NFIF-7a polypeptide encoded by this nucleotide sequence. Invention VII is drawn to a composition comprising an antisense or ribozyme, although these compounds are nucleic acid sequences they do not encode an NFIF polypeptide, they are structurally distinct from polypeptides and antibodies, and they are disclosed as functioning to lower the expression of NFIF in a patient. Invention VIII is drawn to a composition comprising an antibody, this antibody is structurally distinct from both nucleic acids and polypeptide sequences, and they are disclosed as having a distinct function, namely for lowering the activity of an NFIF polypeptide.

5. Inventions I-II, and IX-X are unrelated since the methods of inventions IX-X are not disclosed as being capable of practice with the nucleic acid molecules of inventions I-II since the method is based upon identifying compounds effective to inhibit NFIF polypeptide "activity," not expression.
6. Inventions V-VI, and III-IV are unrelated since the methods of Inventions V-VI require the use of an expression vector that encodes an NFIF polypeptide in a patient, the method does not expressly recite the direct use of the NFIF polypeptides according to inventions III-IV in the claimed method of gene therapy.
7. Inventions VII-VIII and Inventions V-VI are unrelated since the methods of inventions V-VI are drawn to a method for increasing expression of NF $\kappa$ B, and the compositions of inventions VII-VIII are disclosed as being effective to lower the expression of NFIF, wherein the NFIF-7a and NFIF-14b are activators of NF $\kappa$ -B.
8. The methods of inventions V-VI and IX-X are drawn to different methods comprising the use of different components, different steps, different objectives and different outcomes.
9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
10. Because these inventions are distinct for the reasons given above and the search required for each of inventions I-IV is separate and unique, restriction for examination purposes as indicated is proper.
11. A telephone call was made to Patrick J. Kelly, Ph.D. on 6-19-03 to request an oral election to the above restriction requirement, but did not result in an election being made.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Priority***


14. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on 7-26-2000. It is noted, however, that applicant has not filed a certified copy of the 0018307.9 application as required by 35 U.S.C. 119(b).

Art Unit: 1635

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Fri, 8:30AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Janet L. Epps-Ford, Ph.D.  
Examiner  
Art Unit 1635

*JLE*

June 19, 2003